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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/669,971	09/24/2003	Nathan A. Winslow	5490-000337	4885

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EXAMINER	
BLANCO, JAVIER G	

ART UNIT	PAPER NUMBER
3738	

MAIL DATE	DELIVERY MODE
05/21/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/669,971	WINSLOW, NATHAN A.	
	Examiner	Art Unit	
	Javier G. Blanco	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 April 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5-15,17,19-22 and 24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3, 5-15, 17, 19-22, and 24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/5/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 5, 2007 has been entered.

Response to Amendment

2. Applicant's amendment of claims 1, 2, 13, 19, and 24 in the reply filed on April 5, 2007 is acknowledged.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-3, 6-13, 15, 17, 19-22, and 24 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Chibrac et al. (US PG Pub No 2002/0022889 A1).

Referring to Figures 2b, 3b, 4a, and 7, Chibrac et al. disclose a monolithic resurfacing humeral implant (see paragraph 0053 and 0080) comprising:

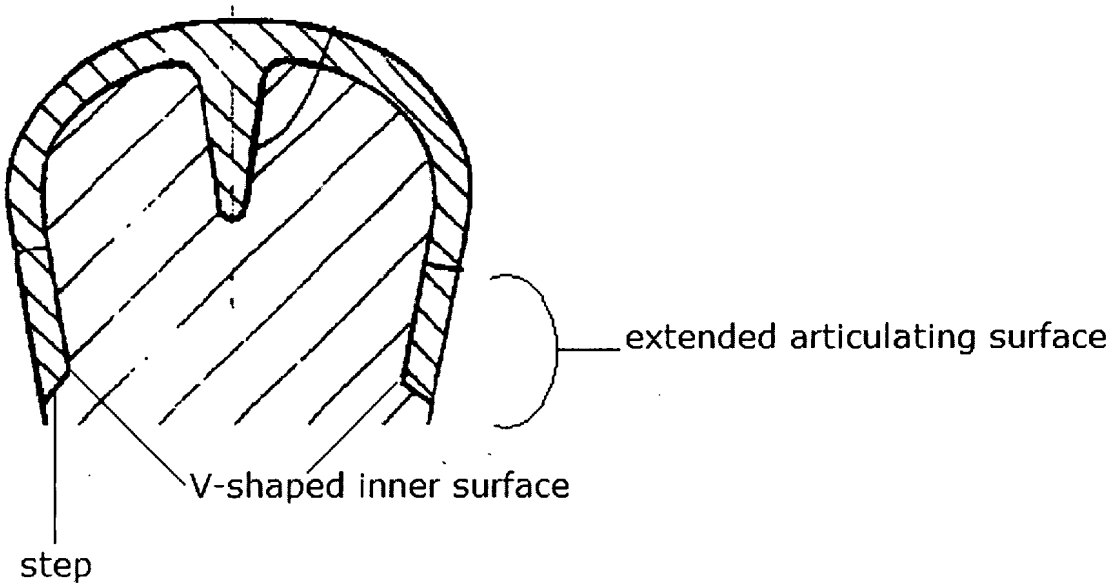
(i) A hemispherical exterior articulating surface (contact surface C);

(ii) A concave interior surface (fixing surface F) opposite said exterior articulating surface;

(iii) An integral (i.e., unitary) straight, tapered anchoring device (anchoring element A) having a textured outer surface (see paragraph 0063), said anchoring device extending from said interior surface; and

(iv) An extended articulating surface (see Figures 2b and 3b) protruding from a portion of said hemispherical exterior articulating surface, said extended articulating surface having at least one planar second interior surface, including a planar "V" shaped inner surface. Chibrac et al. also disclose the method as claimed in claims 19-22 and 24 (see paragraphs 0051, 0053-0057, 0063, 0069, and 0079-0081), including resecting the humeral head to form planar surfaces (i.e., resected portions 58 and 59 are disclosed as "substantially plane", as disclosed in paragraph 0079). The term "planar" is generally defined as: "Of, relating to, or situated in a plane"; "of, relating to, or lying in a plane". The "extended articulating surface" of the Chibrac et al. implant comprises a second interior surface "situated in a plane" or "lying in a plane".

Figure 2b of Chibrac et al. (US PG Pub No 2002/0022889 A1) shown below:



5. Claims 1-3 and 6-10 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by BIOMET brochure (engineering drawings submitted 7/22/1997, and cited in Applicant's IDS of 12/17/2003).

Referring to Drawings 1-4, the BIOMET brochure disclose a monolithic resurfacing humeral implant comprising:

(i) A hemispherical exterior articulating surface;

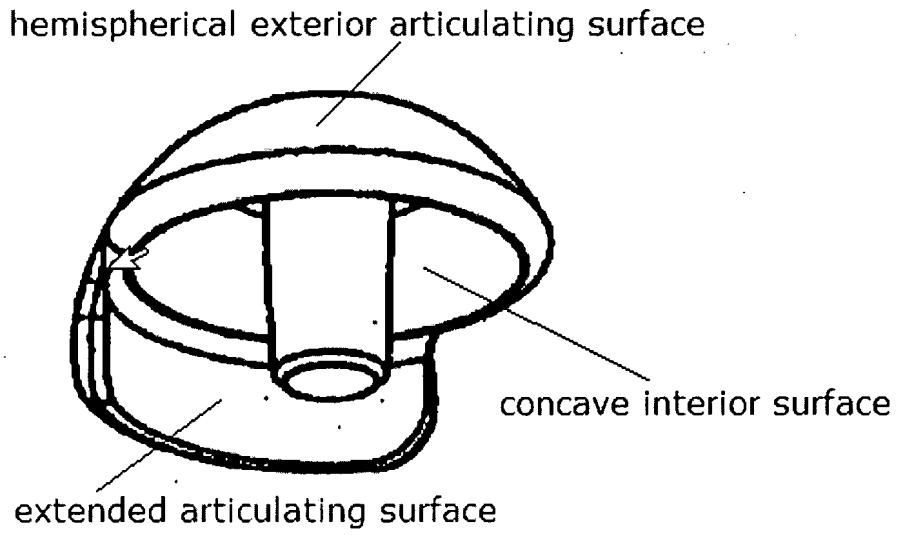
(ii) A concave interior surface opposite said exterior articulating surface;

(iii) An integral (i.e., unitary) straight, tapered anchoring device (see drawings) having a textured outer surface (brochure disclosed it as a glass bead blast), said anchoring device extending from said interior surface; and

(iv) An extended articulating surface protruding from a portion of said hemispherical exterior articulating surface, said extended articulating surface having at least one planar second interior surface. The term "planar" is generally defined as: "Of, relating to, or situated in a plane"; "of,

relating to, or lying in a plane". The "extended articulating surface" of the BIOMET implant (see main (fourth) drawing of the BIOMET brochure below) comprises a second interior surface "situated in a plane" or "lying in a plane". The second (i.e., lateral view) and fourth (i.e., main or fourth) drawings show the extended articulating surface as comprising a "step".

Main (fourth) drawing of the BIOMET brochure shown below:



Response to Arguments

6. With regards to the 102(b) rejection based on BIOMET brochure (engineering drawings submitted 7/22/1997, and cited in Applicant's IDS of 12/17/2003), Applicant's arguments filed April 5, 2007 have been fully considered but they are not persuasive.

a. The Applicant argues that the implant shown in the BIOMET brochure does not disclose the anchoring device (i.e., stem) as having a textured outer surface. The Examiner respectfully

disagrees. As previously indicated in the rejection (above), the brochure disclosed said textured outer surface as a glass bead blast.

b. The Applicant argues that the implant shown in the BIOMET brochure does not disclose newly added limitation "said extended articulating surface having at least one planar second interior surface". The Examiner respectfully disagrees. The term "planar" is generally defined as: "Of, relating to, or situated in a plane"; "of, relating to, or lying in a plane". The "extended articulating surface" of the BIOMET implant (see main (fourth) drawing of the BIOMET brochure above) comprises a second interior surface "situated in a plane" or "lying in a plane".

7. Claims 19, 20, and 24 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Rambert et al. (FR 2 578 739; cited in Applicant's IDS).

Referring to Figures 1-3, Rambert et al. disclose a monolithic resurfacing humeral implant comprising:

(i) A hemispherical exterior articulating surface (exterior surface of spherical cap 2);

(ii) A concave interior surface (interior surface of spherical cap 2) opposite said exterior articulating surface;

(iii) An integral (i.e., unitary) straight, tapered anchoring device (anchoring pin 7 and/or bush 4) having a textured outer surface (threads or flutes of bush 4), said anchoring device extending from said interior surface; and

(iv) An extended articulating surface (8) protruding from a portion of said hemispherical exterior articulating surface, said extended articulating surface having at least one planar second interior

surface. The term "planar" is generally defined as: "Of, relating to, or situated in a plane"; "of, relating to, or lying in a plane".

Response to Arguments

8. With regards to the 102(b) rejection based on Rambert et al. (FR 2 578 739; cited in Applicant's IDS), Applicant's arguments filed April 5, 2007 have been fully considered but they are not persuasive.

a. With regards to independent claim 19, the Applicant argues Rambert et al. does not teach: "positioning an extended articulating surface of the resurfacing humeral head implant in a lateral region of the humeral head". The Examiner respectfully disagrees. As shown in Figure 3, the extended articulating surface (8) is positioned in a lateral region of the humeral head.

9. Claims 1-3, 6-13, 15, 17, 19-22, and 24 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Long et al. (US PG Pub No 2004/0193277 A1).

Referring to Figures 7-23, Long et al. disclose a monolithic resurfacing humeral implant comprising:

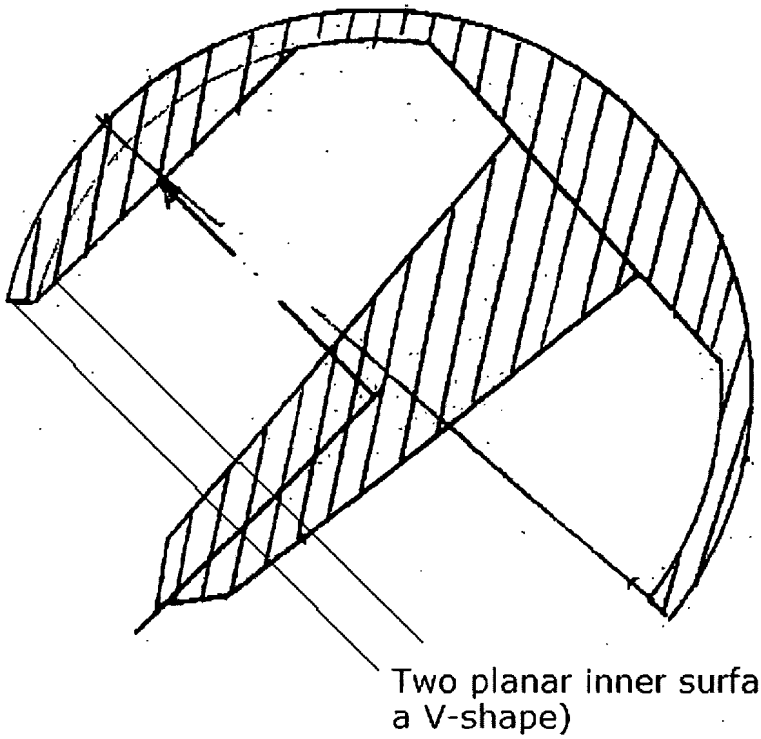
(i) A hemispherical exterior articulating surface (first body articulating surface 24);

(ii) A concave interior surface (interior surface of first body 22) opposite said exterior articulating surface;

(iii) An integral (i.e., unitary) straight, tapered anchoring device (stem 36) having a textured outer surface (see blasted surface shown in Figure 10), said anchoring device extending from said interior surface; and

(iv) An extended articulating surface (second body articulating surface 32 of second body 30) protruding from a portion of said hemispherical exterior articulating surface, said extended articulating surface having at least one planar second interior surface, including a planar "V" shaped inner surface (see Figures 21 and 22). Long et al. also disclose the method as claimed in claims 19-22 and 24 (see pages 4-6), including resecting the humeral head to form planar surfaces. The term "planar" is generally defined as: "Of, relating to, or situated in a plane"; "of, relating to, or lying in a plane". The "extended articulating surface" of the Long et al. implant comprises a second interior surface "situated in a plane" or "lying in a plane".

Figure 22 of Long et al. (US PG Pub No 2004/0193277 A1) shown below:



Response to Arguments

10. With regards to the 102(b) rejection based on Long et al. (US PG Pub No 2004/0193277 A1), Applicant's arguments filed April 5, 2007 have been fully considered but they are not persuasive.

a. The Applicant argues that the Long et al. implant does not disclose newly added limitation "said extended articulating surface having at least one planar second interior surface". The Examiner respectfully disagrees. The term "planar" is generally defined as: "Of, relating to, or situated in a plane"; "of, relating to, or lying in a plane". The "extended articulating surface" of the Long et al. implant comprises a second interior surface "situated in a plane" or "lying in a plane".

11. Claims 19, 20, and 24 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by the disclosure of Copeland™ Humeral Resurfacing Head (Biomet Orthopedics, Inc.: 2000 brochure).

Referring to Figures 1-18, and the pictures on page 1, the brochure discloses a method for resurfacing a humeral head of an implant site, the method comprising:

(i) Resurfacing the humeral head (see Figures 1-15; see entire document, particularly pages 3-7);

(ii) Positioning a resurfacing humeral head implant (Copeland™ Humeral Resurfacing Head comprising a dome-shaped outer surface, a concave inner surface, and a tapered post having flutes and a blasted finish) on the resurfaced surface of the humeral head (see Figures 1-17; see entire document, particularly pages 3-8); and

(iii) Positioning an extended articulating surface (i.e., the circumferential edge) of the resurfacing humeral head implant in a lateral region (a "lateral region" is broadly interpreted) so as to articulate with at least one of a bone and a ligament (see Figures 16 and 17; see entire document).

It should be noted that, from the claim language of independent claim 19, an arbitrary line or boundary distinguishes/defines the "extended articulating surface". It should also be noted that the circumferential edge of the implant "articulates with least one element of an coracoacromial arch" (see Figure 16). The brochure shows (see Figures 11-15) using a jig (i.e., a guide) and a trial implant.

Response to Arguments

12. With regards to the 102(b) rejection based on Copeland™ Humeral Resurfacing Head (Biomet Orthopedics, Inc.: 2000 brochure), Applicant's arguments filed April 5, 2007 have been fully considered but they are not persuasive.

a. The Applicant argues that Copeland™ Humeral Resurfacing Head (Biomet Orthopedics, Inc.: 2000 brochure) does not disclose: "resecting the humeral head so as to form a planar surface". The Examiner respectfully disagrees. The term "planar" is generally defined as: "Of, relating to, or situated in a plane"; "of, relating to, or lying in a plane".

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over BIOMET brochure (engineering drawings submitted 7/22/1997, and cited in Applicant's IDS of 12/17/2003) in view of Pappas et al. (US 4,470,158).

The BIOMET brochure discloses the invention as claimed in claims 1-3 and 6-10. The BIOMET brochure did not particularly disclose said extended articulating surface as having "a planar "V" shaped inner surface". However, this is well known in the art. For example, Pappas et al. disclose joint prostheses comprising articulating surfaces having planar "V" shaped inner surfaces (**Figure 2:** inner surface of component 11; **Figures 37-41 and 63:** component/flange 100 comprises an extended articulating surface 106 having a planar "V" shaped inner surface; and **Figure 50:** inner surface of plate section 152) in order to maximize the prosthesis-to-bone contact area, minimize tipping effects resulting from eccentric loads, and minimize compressive stress on the bone (see column 6, lines 39-50 and lines 55-58; column 21, lines 8-15; and column 23, line 54 to column 24, line 9). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have combined the teaching of joint prostheses comprising articulating surfaces having planar "V" shaped inner surfaces, as taught by Pappas et al., with the joint prosthesis shown in the BIOMET brochure, in order to maximize the prosthesis-to-bone contact area, minimize tipping effects resulting from eccentric loads, and minimize compressive stress on the bone.

NOTE: Looking to Applicants' specification (see paragraphs 0022 and 0027), there is no criticality in the use of a "planar "V" shaped inner surface". Furthermore, the Applicant admits

in the present application that "the resection 52 may be of various other shapes or configurations" (see paragraph 0027).

15. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rambert et al. (FR 2 578 739; cited in Applicant's IDS) in view of Pappas et al. (US 4,470,158).

Rambert et al. disclose the invention as claimed in claims 1-3 and 6-10. Rambert et al. did not particularly disclose said extended articulating surface as having "a planar "V" shaped inner surface". However, this is well known in the art. For example, Pappas et al. disclose joint prostheses comprising articulating surfaces having planar "V" shaped inner surfaces (**Figure 2:** inner surface of component 11; **Figures 37-41 and 63:** component/flange 100 comprises an extended articulating surface 106 having a planar "V" shaped inner surface; and **Figure 50:** inner surface of plate section 152) in order to maximize the prosthesis-to-bone contact area, minimize tipping effects resulting from eccentric loads, and minimize compressive stress on the bone (see column 6, lines 39-50 and lines 55-58; column 21, lines 8-15; and column 23, line 54 to column 24, line 9). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have combined the teaching of joint prostheses comprising articulating surfaces having planar "V" shaped inner surfaces, as taught by Pappas et al., with the joint prosthesis of Rambert et al., in order to maximize the prosthesis-to-bone contact area, minimize tipping effects resulting from eccentric loads, and minimize compressive stress on the bone.

NOTE: Looking to Applicants' specification (see paragraphs 0022 and 0027), there is no criticality in the use of a "planar "V" shaped inner surface". Furthermore, the Applicant admits

in the present application that "the resection 52 may be of various other shapes or configurations" (see paragraph 0027).

16. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Long et al. (US PG Pub No 2004/0193277 A1) in view of Copeland™ Humeral Resurfacing Head (Biomet Orthopedics, Inc.: 2000 brochure).

Long et al. disclose the invention as claimed in claims 1-3, 6-13, 15, 17, 19-22, and 24. Long et al. did not particularly disclose the stem as having flutes. However, this is well known in the art. For example, the Copeland brochure discloses a monolithic resurfacing humeral implant comprising a tapered post having flutes/ribs in order to improve the mechanical press-fit and prevent rotation of said implant. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have combined the teaching of a monolithic resurfacing humeral implant comprising a tapered post having flutes/ribs, as taught by the Copeland brochure, with the monolithic resurfacing humeral implant of Long et al., in order to improve the mechanical press-fit and prevent rotation of said implant.

17. Claims 5 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chibrac et al. (US PG Pub No 2002/0022889 A1) in view of Copeland™ Humeral Resurfacing Head (Biomet Orthopedics, Inc.: 2000 brochure).

Chibrac et al. disclose the invention as claimed in claims 1-3, 6-13, 15, 17, 19-22, and 24. Chibrac et al. did not particularly disclose the stem as having flutes. However, this is well known in the art. For example, the Copeland brochure discloses a monolithic resurfacing humeral

implant comprising a tapered post having flutes/ribs in order to improve the mechanical press-fit and prevent rotation of said implant. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have combined the teaching of a monolithic resurfacing humeral implant comprising a tapered post having flutes/ribs, as taught by the Copeland brochure, with the monolithic resurfacing humeral implant of Chibrac et al., in order to improve the mechanical press-fit and prevent rotation of said implant.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 571-272-4747. The examiner can normally be reached on M-F (9:30 a.m.-7:00 p.m.), first Friday of the bi-week off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300 for regular communications and After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Javier G. Blanco

May 3rd, 2007

David H. Willse
Primary Examiner